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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/31/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/268,437

Applicant(s)

DING ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 7/2/03 in Paper No. 27 is acknowledged and has been entered. Claim 11 has been added. Accordingly, claims 1-5 and 11 are pending and are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-5 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Henkens et al. (US 6,391,558).

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Henkens et al. disclose a simultaneous electrochemical assay device (biosensor array device) comprising a cell (circuit board) for holding a sample, having a plurality of plurality of working electrodes and reference, i.e. auxiliary, electrodes. Each of the working electrodes is adjacent, i.e. linked or attached to, an analyte binding area which has an analyte binding substrate and separate from other analyte binding areas by a distance (surface area). Analyte binding substrates (bioreporter molecules) comprise of different analyte specific proteins such as antigens, antibodies, and enzymes (reductases, peroxidases, phosphatases). See column 4, line 41 to column 6, line 38 and column 19, line 58 to column 20, line 56. The plurality of working electrodes quantitatively measure enzymatic reaction product. See column 17, line 51 to column 18, line 63 and column 41, lines 31-38. The device does not include a means to mix the sample in the cell.

3. Claims 1-5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US 5,063,081).

Cozzette et al. disclose a simultaneous electrochemical assay device (amperometric base sensor) fabricated on a substantially planar silicon substrate comprising a unit cell for holding a sample, having a plurality of working (catalytic) electrodes with identical geometry and area, and having analyte binding areas (biolayer) and enzyme incorporated thereto, wherein the working electrodes quantitatively measure enzymatic reaction product (see column 3, lines 12-28, column 13, lines 22-53, column 19, lines 23-45, column 15, line 63 to column 16, line 42, and column 22,

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lines 18-36). The unit cell may be repeated in a geometric array several hundred times on a single silicon wafer. Each working electrode is surrounded by an auxiliary (combined counter and reference) electrode. Each of the working electrodes are adjacent to permselective silane layer having immobilized thereon, the analyte binding areas which are localized on the electrode portions of the unit cell and separated from adjacent analyte binding areas by a distance (see column 25, line 35 to column 26, line 4). The working electrodes on analyte binding areas are overlain and aligned with analyte specific proteins such as antigens and antibodies (biolayer and bioactive molecules) (see column 22). The device does not include a means to mix the sample in the cell.

Response to Arguments

4. Applicant's arguments filed 7/2/03 have been fully considered but they are not persuasive.

A) Applicant argues that Henkens et al. do not anticipate the claimed invention the reference discloses and requires a separate reference electrode for each working electrode, whereas the claimed invention uses only one common reference electrode for the plurality of working electrodes.

In response to applicant's argument that the references fail to show using only one common reference electrode for the plurality of working electrodes, it is noted that such features upon which applicant relies is not recited in the rejected claims. The claims, as currently recited, do not exclude use of more than one reference electrode.

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Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

B) Applicant argues that Henkens et al. is not designed to test multiple analytes simultaneously.

In response, the recitation "simultaneous" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that the electrochemical devices of Henkens are not designed to test multiple analytes (simultaneously), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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C) Applicant argues that Henkens et al. reference discloses bonding the analyte binding area directly to the electrodes as opposed to adjacent the electrode.

In response, the claimed invention recites "each working electrode adjacent to one analyte binding area" and does not exclude the analyte binding area being "linked" to the analyte binding area as disclosed by Henkens at column 4, lines 43-46.

D) Applicant argues that Henkens et al. only disclose a separate well for each different electrode.

In response, Henkens et al. at column 20, lines 53-56 disclose that three electrodes are contained in a bean-shaped depression which serves as a sample well; thus, the Henkens et al. reference reads on the language recited in claim 1 as follows: "said cell having ... a plurality of working electrodes".

E) Applicant argues that Cozzette et al. do not anticipate the claimed invention the reference discloses and requires a separate reference electrode for each working electrode, whereas the claimed invention uses only one common reference electrode for the plurality of working electrodes.

In response to applicant's argument that the references fail to show using only one common reference electrode for the plurality of working electrodes, it is noted that such features upon which applicant relies is not recited in the rejected claims. The claims, as currently recited, do not exclude use of more than one reference electrode. Although the claims are interpreted in light of the specification, limitations from the

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specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

F) Applicant argues that Cozzette et al. is not designed to test multiple analytes simultaneously.

In response, the recitation "simultaneous" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that the electrochemical devices of Cozzette are not designed to test multiple analytes (simultaneously), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

5. No claims are allowed.

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6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

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Gailene R. Gabel

Patent Examiner

Art Unit 16641

October 28, 2003 *GG*

Christopher L. Chin

CHRISTOPHER L. CHIN

PRIMARY EXAMINER

GROUP ~~1800~~ 1641